

Attorney Docket No. P66925US1
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Remarks/Arguments:

Claims 6-10, previously presented, claim 11, currently amended, and claims 12 and 13, presented hereby, are pending.

Claims 1-5 are canceled without prejudice or disclaimer.

Claim 11 is amended to correct an apparent clerical error, by changing "palsy" to "paresis." The correct word—paresis—is found in original claim 7 and at page 2, line 11, of the specification. The subject matter of new claims 12 and 13 are found in original claims 7 and 5, respectively.

Claims 6-11 were rejected under §102(b) as allegedly anticipated by US5,981,601 (Nagley). Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*).

The rejected claims are limited to (1) a "spray," which contains (2) "ubiquinone Q-10" in (3) an "aqueous colloidal dispersion." Nagley fails to meet limitation (3)—the "aqueous colloidal dispersion."

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Nagley discloses (column 3, starting from line 50) a pharmaceutical composition comprising a redox compound, which may be Q10. The reference further discloses (Nagley column 8, line 16) that the pharmaceutical composition may be in form of a "spray" or an "aerosol," which disclosure is apparently relied on in the statement of rejection (Office Action, page 2) to meet limitations (1)—the "spray"—and (3)—the "aqueous colloidal dispersion," on the rejected claims. However, the reliance is misplaced; neither the "spray" nor the "aerosol" disclosed in Nagley meets the limitation to "an aqueous colloidal dispersion," as recited in the rejected claims.

In alleging that the limitation "an aqueous colloidal dispersion" reads on either the disclosed "spray" or "aerosol," the rejection must rely on the theory of *inherency*, i.e., the "aqueous colloidal dispersion" is an allegedly inherent characteristic of the "spray" or "aerosol" disclosed in Nagley. However, the reference disclosure fails to satisfy the standards for establishing lack of patentability based on teachings inherently disclosed in a reference.

For the doctrine of inherency to apply it must be "*inevitable*" from the teachings of the prior art. *In re Wilding*, 190 USPQ 59, 62 (CCPA 1976) (*emphasis added*). "In relying on a theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (*emphasis in original*). Before "the burden shifts," the examiner has "the initial burden of establishing a prima facie basis for the alleged inherency." 17 USPQ2d at 1463-64. To base a rejection on what is allegedly inherent in the reference teachings,

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the examiner must . . . reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the applied prior art.

17 USPQ2d at 1464 (*emphasis in original*).

The limitation "aqueous colloidal dispersion" on the rejected claims is not an inevitable feature of either the "spray" or the "aerosol" disclosed in Nagley. For example, neither the "spray" nor the "aerosol" is necessarily "aqueous" (i.e., water containing). As taught in the reference (Nagley, column 8, lines 16-17), itself, the "spray" and the "aerosol" can be based on "vaseline, linoline, polyethylene glycols, alcohols, and combinations of two or more thereof," each of which is non-aqueous.

In that the limitation "aqueous colloidal dispersion" on the rejected claims is not an "inevitable" characteristic of either the "spray" or the "aerosol" disclosed in Nagley, the limitation is not inherently disclosed in the reference. *Wilding*, 190 USPQ at 62. Accordingly, a limitation on the rejected claim being absent from Nagley, anticipation based on Nagley is negated. *Kolster Speedsteel A. B., supra*. Withdrawal of the rejection of claims 6-11 under §102(b) appears to be in order.

Moreover, claim 7 is further (independently) novel over Nagle. Claim 7 limits the spray of claim 6 to "an oral or nasal spray." On the other hand, the disclosure of "aerosol" and "spray," relied on to meet the rejected claims (Nagley, column 8, lines 14-20), is actually limited to "topical application to the skin," i.e.,

Formulations suitable for topical application to the skin preferably take the form of an ointment, cream, lotion, paste, gel, spray, aerosol, or oil. Carriers which may be

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used include vaseline, linoline, polyethylene glycols, alcohols, and combinations of two or more thereof. The active compound is generally present at a concentration of from 0.1 to 15% w/w, for example, from 0.5 to 2% w/w.

Once again, the rejection must rely on the theory of inherency, i.e., since the disclosure relied on mentions neither "oral" nor "nasal," the rejection must rely on either one being an inherent characteristic of spray "Formulations suitable for topical application to the skin." However, the limitation "oral or nasal spray," on rejected claim 7, is not inherent in the reference disclosure.

The aforesaid quoted passage from Nagley teaches that the disclosed "spray" can be based on "polyethylene glycols," a formulation suitable for application to the skin but not, however, suitable for application to the "oral or nasal" mucosa, as required in rejected claim 7. Since the "spray" disclosed in Nagley is not necessarily suitable as the "oral or nasal spray" to which rejected claim 7 is limited, the limitation is not inherently disclosed by the "spray" in Nagley. *Wilding*, 190 USPQ at 62.

The disclosed "Formulations" in Nagley fail to meet the "oral or nasal spray" (emphasis added) limitation on rejected claim 7. Since a limitation on rejected claim 7 is absent from Nagley, anticipation of claim 7 by Nagley is negated. *Kolster Speedsteel A B, supra*. Withdrawal of the rejection as applied against claim 7 appears, further, to be in order.

Each of rejected claims 8 and 10 defines a method of treating specifically recited pathological conditions by administration of the "spray" of claim 6. Limitation to "the treatment of pain conditions from neural disorders" (claim 8) is absent from Nagley. The limitation "treatment of depression, psychosis, or lack of concentration" is absent from Nagley; it being particularly noted

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that "lack of concentration" is not Alzheimer's disease. Additionally, all of the pathological conditions treated in accordance with new claims 12 and 13 are absent from Nagley.

Accordingly, limitations on rejected claims 8 and 10 being absent from Nagley, anticipation based on Nagley is negated. *Kolster Speedsteel A.B. supra*. Withdrawal of the rejection of claims 8 and 10 under §102(b) appears, further, to be in order.

Applicant further submits that Nagley describes experiments wherein the cytotoxic effects of AZT and AMT are ameliorated as shown by treatment of cell lines or a rat animal model. While the cell experiments last over days, the animal model requires treatment for weeks; see for example 16. On the other hand, due to the improved formulation, the presently claimed spray provides faster effects.

Claims 6-8 were rejected under 35 USC 102(e) for allegedly being anticipated by US6200550 (Masterson). Reconsideration is requested.

Masterson describes oral care compositions, e.g., tooth paste, dental gel, sprays, and the like, containing Q10. Diseases mentioned in Masterson (column 4, lines 60 to 65) refer to the oral cavity, for example, gingivitis and periodontitis. The oral care compositions can be in the form of a mouth spray.

Masterson does not disclose the "aqueous colloidal dispersion" limitation on the rejected claims. It does not disclose the treatment of "pain conditions" whatsoever, let alone those resulting from "neural disorders," as required in rejected claim 8.

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Masterson's disclosure of a mouth spray does not inherently meet the limitation "aqueous colloidal dispersion" on the rejected claims. Since the reference simply does not require that the mouth spray be in the form of "an aqueous colloidal dispersion," the limitation is not an inevitable characteristic of the disclosed mouth spray. *Wilding*, 190 USPQ at 62. Since this limitation—both expressly and inherently—is absent from Masterson, anticipation by Masterson is negated. *Kolster Speedsteel A.B. supra*. Accordingly, withdrawal of the rejection under §102(e) based on Masterson appears to be in order.

Furthermore, since the treatment of "pain conditions from neural disorders" as recited in rejected claim 8 being absent from Masterson, anticipation by Masterson is, further, negated. *Kolster Speedsteel A. B. supra*. Withdrawal of the rejection of claim 8 under 35 U.S.C. 103(e) appears, further, to be in order.

Claims 6-11 were rejected under 35 USC 103(a) as allegedly obvious based on Masterson in view Nagley. Reconsideration is requested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the

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cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The "evidence upon which the examiner relies must clearly indicate that a worker of routine skill in this art would view the claimed invention as being obvious." *Ex parte Wolters*, 214 USPQ 735, 736 (BPA&I 1982). "It is facts which must support the legal conclusion of obviousness." *Ex parte Crissy*, 201 USPQ 689, 695 (POBdApp 1976).

The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it may doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

In re Warner, 154 USPQ 173, 178 (CCPA 1967) (*emphasis in original*). An argument by the PTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). When the

USPTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears *in the reference*.

28 USPQ2d at 1957 (*emphasis added*).

As explained, above, neither Masterson nor Nagley supports the limitation "aqueous colloidal dispersion" on the rejected claims. Since "the cited references do not support each limitation" on the rejected claims, the rejection under 35 U.S.C. 103(a) is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Withdrawal of the rejection under §103(a) appears to be in order.

The presently claimed invention provides a spray, and its method of use, the application of which results in fast absorption through the mucosa to effect treatment of diseases related to a neural disorders such as pain, migraine, neuropathy, depression, psychoses, lack of concentration,

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Alzheimer's, Parkinson's and the like. This effect is a property of the presently claimed invention that must be taken into consideration when comparing the claims against the prior art, even though it is not recited in the present claim. *In re Estes*, 164 USPQ 519 (CCPA 1970). Since the property is neither taught nor suggested by Masterson or Nagley, taken alone or in combination, the present claims are patentable over the cited references—under §102(b), §102(e), and §103(a). From the standpoint of patent law, a compound and all of its properties are inseparable." *In re Papesch*, 137 USPQ 43, 51 (CCPA 1963).

***Request for Acknowledgment of
Foreign Priority Under 35 USC 119***

A claim to foreign priority under 35 USC 119 has been made (inventorship declaration of record) and receipt of the certified copy of the priority document acknowledged in parent application no. 09/890,277 (Office Action mailed August 14, 2002).

Accordingly, request is made that the Examiner mark the next Office Action to acknowledge, both, the claim to §119 priority and receipt of the certified copy.

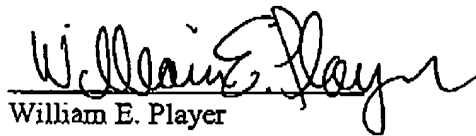
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Favorable action is requested.

Respectfully submitted,

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